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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,257	01/30/2006	Herbert Schwarz	HABERMANN-1	5164

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EXAMINER	
YAO, LEI	
ART UNIT	PAPER NUMBER
1642	
MAIL DATE	DELIVERY MODE
03/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,257	SCHWARZ ET AL.	
	Examiner	Art Unit	
	LEI YAO	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *30 January 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-12 and 22-25, drawn to a method of treating CD137 expression tumor by in vivo administering a CD137 antagonist.

Group 2, claim(s) 13-16, drawn to a method of treating undesired or overactive immune response using CD137 or functional analogues.

Group 3, claim(s) 17-18, drawn to a method of treating undesired or overactive immune response using agonistic anti-CD137 ligand antibody.

Group 4, claim(s) 19-21 and 26, drawn to a method for treating a patient suffering from undesired or overactive immune response comprising administring CD137 or its analogue AND agonistic antibody.

> A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

According to PCT rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. All the groupings are directed to method of using antagonist, analogous, agonist of CD137, or in combination, but each group has different special technical feature not sheared by the remaining groups. Group 1 is directed to antagonist comprising antibody, antisense, or siRNA of CD137, each has the special technical feature not shared by any of the remaining groups. Groups 2-4 are directed to a method of inhibit overactive immune response

with analogous, antibody agonist or combination, each has the special technical feature of different amino acid structures not sheared each other or by any of the remaining groups.

Further election required under 35 U.S.C. 121:

If applicants elect group I, elect one single antagonist listed below:

Specific antibody; peptide; organic small molecule; antisense oligonucleotide; siRNA; antisense expression vector; recombinant virus.

For example, elect peptide.

This application is an internationally filed application filed under 35 U.S.C. 371 and is subject to the rules discussed under MPEP § 1850 (see the last paragraph under MPEP § 803.04, which references the appropriate section for internationally filed applications). Under Markush practice for international applications, the following criteria are required:
(A) the alternatives have a common property or activity and (B) a common core structure is present; or (C) in cases where the core structure cannot be the unifying criteria, all alternatives must belong to the same recognized class of chemical compounds, that is, that the same result will be achieved when one member of the Markush group is substituted for another.

In the instant case, all the listed antagonists do not share a common core structure or common property. Therefore, they do not meet the criteria for (A) and (B) and do not belong to the same recognized class of chemical compounds (C). Since the antagonist do not share the same or corresponding special technical feature under the specific criteria for Markush practice, they lack unity of invention and are not considered alternative species to one another.

In order to be fully responsive, Applicant must elect one from Groups 1-4, one from Group A even though the requirement is traversed. Applicant is advised that neither 1-4, nor A is species election requirements; rather, each of 1-4 and A is a restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of

inventorship must be accompanied by a request under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election/Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

A) B cell lymphoma, tumor of the vulva, nephroblastoma, cystadenocarcinoma of the ovary, rhabdomysarcoma, leiomyosarcoma, fibrosarcoma, immunocytoma, non-Hodgldn lymphoma, carcinoma of the portio uteri, basal cell carcinoma.

B) BBK-2, 4B4-1

C) Autoimmune diseases, allergies, asthma and organ transplant rejection.

If Applicant elect group 1, Applicant is required under 35 U.S.C. 121 to elect one single disclosed species, a tumor, from A) and one single disclosed species, an antibody, from B) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, elect B-cell lymphoma and antibody, 4B4-1.

If Applicant elect any group from groups 2-4, Applicant is required under 35 U.S.C. 121 to elect one single disclosed species from C) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, autoimmune disease.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons each species has the unique structure, function and characteristics, which do not shared by the other species.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lei Yao, Ph.D./
Examiner, Art Unit 1642

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/539,257	SCHWARZ ET AL.	
	Examiner	Art Unit	
	LEI YAO	1642	